

HL7 SPL Working Group Process Communication Forum Telecon  
Wednesday, Nov 18, 2009

Check out the SPL Working Group WIKI @:

<http://spl-work-group.wikispaces.com>

**Questions on SPL:**

ER/DL regulatory questions? Send to [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov)

SPL technical questions? Send to [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov)

**Meeting Minutes:**

**FDA Draft Guidance: SPL Technical Q&As**

**General Feedback on Background and Scope:  
{thanks to S Bass for providing this!}**

... thought the background provided in the "Guidance for Industry - SPL Standard for Content of Labeling Technical Qs and As" was a great update of the activities over the past 5 years.

It served as an excellent primer starting with the Final Rule requiring the Content of Labeling to be submitted in electronic format published in the Federal Register December 2003. It further took us through the use of a PDF format until the transition to SPL in October 31, 2005. It nicely explained the need for the publication of the first guidance in December of 2005 of the same name (*which also referenced the Guidance for Industry "Providing Regulatory Submissions in Electronic Format - Content of Labeling" of April of 2005*) "to provide easy access to answers to frequently asked questions". It further explained the need to revise the 2005 guidance to provide the "most useful and up-to-date information on SPL submissions". As noted "this revision provides both updated answers to questions previously addressed and information responsive to other questions related to submissions in SPL format". It further noted that "the FDA will update this guidance with additional answers to questions, as warranted".

**Question 3:**

**Q:** Does the FDA have a recommendation on where the cross-reference should be placed?

**A:** Location may vary depending on type of submission, so there is no recommendation on particular locations. Sponsors can talk to the Review Division to check their preferences, also CDER and CBER eSubmission teams

**Q:** When can companies best use this cross-reference? It seems of limited use. One company's business process - CBE filed first, followed by the Drug Listing at a later date. Which wouldn't allow for use of the cross-reference

**A:** Key statement seems to be the second (and third) sentences

If you have already submitted identical content of labeling in a SPL file during the registration and listing process, you need not include the SPL file in your application. Instead, we recommend that you update your application by referencing the SPL file in the registration and listing system.

[Underlining for emphasis]

**Question 5:**

**Q:** Is there still a requirement for annotated PDFs?

**A:** PDF of annotated label still needed; annotated shows links to other parts of the submission.

**Question 6:**

**Q:** URL mentioned in this Q&A is the cross-reference detailed in Question 3?

**A:** Yes

**Q:** Can multiple XML files be placed in the same SPL folder on the eCTD backbone?

**A:** Yes. Not for eList submission, though

**Question 12:**

**Q:** Does FPL of carton and container labels include leaflets?

**A:** Discussion amongst sponsor participants indicated most/all continued to include leaflet PDFs.

**Question 15:**

**Q:** Is there still a requirement for any PDFs?

**A:** In addition to comments on Question 5, PDFs are still very much used within the Office of Generic Drugs

**Question 21:**

**Q:** URL error.

**A:** URL is incorrect (since FDA completely modified their website). URL will be corrected in Final version of Guidance.

**Question 29:**

**Q:** Please clarify what is meant by 'section identifier'.

**A:** Section identifier = GUID

**Question 32:**

**Q:** Please clarify what is meant by 'problem' with the SPL posted.

**A:** This is referencing how the SPL is presented (not a grammatical or editorial change to text)

**Question 34:**

**Q:** Please clarify what is meant by 'current use'.

Comment from participant: Definition of current use: used to be 'USPI in trade package'. If it's on the web site, does that now mean 'current use'?

**A:** No further information at this time

**New validation Procedure Alerts** (posted at <http://spl-work-group.wikispaces.com/Validation+Alerts>)

- zip files
- deprecation of "unapproved drug" term

**FYIs:**

- New eCards (all at <http://spl-work-group.wikispaces.com/SPL+eCards+-+Quick+Reference>)  
Intended as Quick References, the information for each ER/DL scenario is presented in flowchart format.
- SPL Roadmap ([http://spl-work-group.wikispaces.com/file/view/roadmap\\_creating\\_and\\_submitting\\_spl\\_R4.pdf](http://spl-work-group.wikispaces.com/file/view/roadmap_creating_and_submitting_spl_R4.pdf))
- Pragmatics Lite Validator information (<http://spl-work-group.wikispaces.com/Common+Technical+Errors+with+SPL>)

**As of November 18, 2009 there are 5483 SPL on [DailyMed](#)**

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